

STAARVISC™
(Sodium Hyaluronate)
viscoelastic solution

Product Information

Description

STAARVISC™ (Sodium Hyaluronate) is a sterile, nonpyrogenic, non-inflammatory, transparent viscoelastic solution of highly purified sodium hyaluronate dissolved in buffered saline. Sodium hyaluronate is a naturally occurring linear glycosaminoglycan with a repeating disaccharide unit of sodium glucuronate and n-acetylglucosamine linked by a beta 1-3 glycosidic bond. STAARVISC™ is a high molecular weight (800,000 to 1,000,000) fraction of sodium hyaluronate (1.1 to 1.5% total weight) dissolved in a sodium phosphate buffer (pH = 6.9 - 7.5 at 25°C). Viscosity of STAARVISC™ is approximately 140cP at a shear rate of 1000/sec @ 25°C. Approximate refractive index of STAARVISC™ is 1.3353 @ 35°C.

insert log/lot plot of viscosity vs.
shear rate here

Indications: STAARVISC™ is indicated for use as a surgical aid in ophthalmic anterior and posterior segment surgery including:

- Cataract extraction with or without implantation of an intraocular lens
- Corneal transplant surgery
- Glaucoma filtering surgery
- Secondary lens implantation

STAARVISC™ aids in maintaining a deep anterior and posterior chamber, protecting corneal endothelial and surrounding tissues from touch by instruments or intraocular lenses, inflating the capsular bag after cataract extraction and lubricating surgical instruments.

Contraindications: There are no known contraindications for the use of STAARVISC™ sodium hyaluronate when used as recommended.

Precautions: Those precautions normally considered during ophthalmic surgical procedures are recommended. Transient increases in intraocular pressure may occur following surgery because of pre-existing glaucoma or due to the surgery itself. Therefore, for these reasons the following precautions should be considered:

- An excess quantity of STAARVISC™ should not be used and all STAARVISC™ should be removed from the anterior chamber by irrigation or aspiration after surgery.

- The intraocular pressure of patients receiving STAARVISC™ should be carefully monitored. If the postoperative intraocular pressure increases above expected values, appropriate therapy should be administered.
- It is recommended that a single use cannula such as the one provided in this package should be used when instilling STAARVISC™ into the eye. Reuse of the cannula should be avoided. Denaturation and particulate formation in viscoelastics with the repeated use of reusable cannulae has been reported in some studies.
- STAARVISC™ is prepared from a biological source. It is a highly purified fraction extracted from avian tissues and may contain minute amounts of protein. The physician should be aware of potential risks that can occur with the injection of biological material into the eye. Each batch of STAARVISC™ is tested to demonstrate that it is essentially non-inflammatory.

Adverse Reactions: The following adverse reactions have been reported following the use of sodium hyaluronate: increased intraocular pressure, secondary glaucoma, postoperative inflammatory reactions.

How Supplied: STAARVISC™ is a sterile, nonpyrogenic viscoelastic preparation supplied in a disposable glass syringe with a Luer tip and a Luer-Lock cannula. STAARVISC™ syringes are aseptically packaged and sterile if the outer tray package or seal have not been opened or damaged. STAAR Surgical Company recommends that the product be discarded if the integrity of the outer tray package or seal have been opened or damaged. The sterility expiration date is printed on the outer package.

Storage and Handling: STAARVISC™ should be stored at between 2° and 10°C (36° - 50°F). Do not resterilize.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

1. Pape L, Balazs E.A. *The use of Sodium Hyaluronate (Healon®) in Human Anterior Segment Surgery*. Ophthalmol 1980; 87:699.
2. Jensen MK, Crandall AS, Mamalis N, Olson RJ. *Crystallization on Intraocular Lens Surfaces Associated with the use of Healon GV®*. Arch Ophthalmol. 1994;112:1037-1042.

Manufactured for:

STAAR Surgical Company
Monrovia, CA. 91016 (USA)
(626) 303-7902